

Application No.: 09/980,006

Docket No.: 21547-00283-US

REMARKS

Claims 1-21 are pending in the application. Claims 16-18 were previously withdrawn from consideration. Claims 1 and 15 have been amended and claims 4, 8 and 20 have been canceled by way of the present amendment. Reconsideration is respectfully requested.

In the outstanding Office Action, the drawings submitted 5/31/05 were accepted; claims 1, 4, 12 and 20 were objected to due to an inconsistency in the claim language; claims 1-9, 12-15 and 19-21 were rejected under 35 U.S.C. Section 102(b) as anticipated by U.S. Patent No. 3,605,123 (Hahn); and claims 10 and 11 were rejected under 35 U.S.C. Section 103(a) as unpatentable over Hahn.

Claim Objections

Claims 1, 4, 12 and 20 were objected to due to an inconsistency in the claim language. In response to the rejection, claim 1, upon which claims 4, 12 and 20 ultimately depend, and claim 15 have been amended to include the limitation of claim 4 and 20 and to further clarify that the invention is directed toward the combination of the layer and implant. The amended claims clearly raise no issue of new matter since they incorporate limitations from dependent claims 4 and 20. Therefore, Applicant respectfully submits that the claims are now consistent and request the outstanding objection be withdrawn.

102 Claim Rejections

Claims 1-9, 12-15 and 19-21 were rejected under 35 U.S.C. Section 102(b) as anticipated by Hahn. Applicants respectfully traverse the rejection.

Hahn discloses a permanent implant for bone tissue which has a dense cast or wrought base portion of high strength metal, and a porous metal layer overlying and bonded to the base

Application No.: 09/980,006

Docket No.: 21547-00283-US

portion.¹ In particular, Hahn discloses a prosthesis 10 that includes a pin or shaft 11 and ball 12.² In addition, Hahn discloses the prosthesis 10 may be composed of metals such as titanium.³

Further, Hahn discloses the titanium prosthesis 10 is coated, on the pin or shaft 11, with a *thin* porous layer of titanium 13.⁴ In particular, Hahn discloses that the coating thickness is approximately 0.1 inch and the preferred thickness is from about 0.015 to about 0.030 inches.⁵

Moreover, Hahn discloses a process for providing a high strength bond between the coating 13 and base metal shaft 11 using a plasma flame. In particular, Hahn discloses *no* porosity or practically no porosity exists at the interface between the coating 13 and surface of the base metal shaft 11 and gradually increasing porosity, along with pore size and pore density, in moving away from the interface between the surface of the base metal and the coating 13. Furthermore, Hahn discloses renderings of actual photographs of magnified sections of bone 20, 30; pin or shaft 21 and coating 22, 32.⁶

However, Hahn nowhere discloses, as recited in claim 1:

[a] layer (2''') arranged on an implant (1) for bone or tissue structure (5), that constitutes a boundary or barrier for the purpose of increasing retention and has a substantial thickness (T), said layer (2''') further comprising:

a channel network (6) that gives the layer a substantial porosity,

wherein the layer is *established on an undulating or uneven surface (3') present on the implant and having a roughness value in the range of 0.4 - 5 μ m*, for the purpose of increasing the layer volume, and

wherein the channel network (6) is designed with mouths (3, 4) which face towards a surface of the layer and whose respective cross-sectional diameters (D) at the surface (2a') of the layer are substantially less than the respective extents (H) of the channels in and down into the layer as seen from said surface (2a') (emphasis added).

¹ Hahn at Abstract.

² *Id.* at column 3, lines 30-33.

³ *Id.* at column 3, lines 33-35.

⁴ *Id.* at column 3, lines 43-45.

⁵ *Id.* at column 3, lines 47-54.

⁶ *Id.* at FIG. 2, FIG. 3; column 3, lines 55-66; and column 5, lines 25-42.

Application No.: 09/980,006

Docket No.: 21547-00283-US

That is, Hahn nowhere discloses a layer, “established on an undulating or uneven surface present on the implant and having a roughness value in the range of 0.4 - 5 μm ,” as recited in claim 1 (emphasis added).⁷ More specifically, Applicant respectfully submits that this limitation, as recited in original dependent claims 4 and 20, has not been explicitly addressed in previous Office Actions.

In addition, Hahn nowhere discloses “contiguous channel branches” that “extend through at least a greater part of the layer from said surface to a transition from the layer to the implant,” as recited in claim 2. Furthermore, Hahn nowhere discloses “the layer has high degree of porosity, with a number $1 \times 10^7 - 1 \times 10^{10}$ pores/cm³,” as recited in claim 9. Further, independent claim 15 contains similar wording to that recited in claim 1 and, as noted above, the limitations of this wording are *not* disclosed by Hahn. Moreover, Applicant respectfully submits that this limitation has not been explicitly addressed in previous Office Actions.

Thus, it is respectfully submitted that Hahn does not disclose, anticipate or inherently teach the limitations of claims 1-3, 5-7, 9, 12-15 and 19-21. Therefore, it is respectfully submitted that claims 1 and 15, and claims dependent thereon, patentably distinguish over Hahn.

103 Claim Rejections

Claims 10-11 were rejected under 35 U.S.C. Section 103(a) as unpatentable over Hahn. Applicants respectfully traverse the rejection.

Claims 10-11 are dependent on claim 1. As discussed above, claim 1 is not disclosed by Hahn. Therefore, at least for the reasons discussed above, claims 10 and 11 are not disclosed by Hahn.

The outstanding Office Action attempts to overcome the deficiencies of Hahn with the suggestion of obviousness.⁸ However, obviousness cannot overcome all of the deficiencies of Hahn as discussed below.

Claims 10 and 11 are ultimately dependent upon claim 1. Hahn nowhere discloses, as recited in claim 1:

⁷ *Id.* at column 3, lines 55-66.

⁸ Outstanding Office Action at page 9, lines 4-14.

Application No.: 09/980,006

Docket No.: 21547-00283-US

[a] layer (2''') arranged on an implant (1) for bone or tissue structure (5), that constitutes a boundary or barrier for the purpose of increasing retention and has a substantial thickness (T), said layer (2''') further comprising:

a channel network (6) that gives the layer a substantial porosity,

wherein the layer is established on an undulating or uneven surface (3') present on the implant and having a roughness value in the range of 0.4 - 5 μm , for the purpose of increasing the layer volume, and

wherein the channel network (6) is designed with mouths (3, 4) which face towards a surface of the layer and whose respective cross-sectional diameters (D) at the surface (2a') of the layer are substantially less than the respective extents (H) of the channels in and down into the layer as seen from said surface (2a') (emphasis added).

As discussed above, Hahn nowhere discloses a layer, "established on an undulating or uneven surface present on the implant and having a roughness value in the range of 0.4 - 5 μm ," as recited in claim 1 (emphasis added).⁹ More specifically, Applicant respectfully submits that the limitations in original dependent claims 4 and 20 have not been explicitly addressed in previous Office Actions.

In addition, claim 1 recites: "mouths (3, 4) which face towards a surface of the layer and whose respective cross-sectional diameters (D) at the surface (2a') of the layer are substantially less than the respective extents (H) of the channels," as recited in claim 1.¹⁰ Further, claim 10 recites:

wherein the surface has pores or channel mouth areas with diameters or surface area sizes in the range of 0.1 - 10 μm , and or in that the total channel network or pore volume lies in a range of 5 x 10⁻² and 10⁻⁵ cm³

It is respectfully submitted that Hahn nowhere explicitly addresses the dimensions of the channels (i.e., "D" and "H" as recited in claim 1) or any relationship between these dimensions. Moreover, Applicant respectfully submits that this limitation has not been explicitly addressed in previous Office Actions.

⁹ *Id.* at column 3, lines 55-66.

¹⁰ *Id.* at column 3, lines 55-66.

Application No.: 09/980,006

Docket No.: 21547-00283-US

Thus, it is respectfully submitted that Hahn nowhere discloses, suggests or makes obvious the limitations of claim 1 and even more specifically, the limitations of claims 10 and 11, which ultimately depend upon claim 1. Therefore, claims 10 and 11, and claims dependent thereon, patentably distinguish over Hahn.

Conclusion

In view of the above amendments and remarks, reconsideration and allowance of the pending claims are respectfully requested.

Applicants believe that the present application is in condition for allowance, and an early indication of the same is respectfully requested.


If the Examiner has any questions or requires clarification, the Examiner may contact the undersigned so that this Application may continue to be expeditiously advanced. In the event the Examiner believes an interview might serve to advance the prosecution of this application in any way, the undersigned is available at the telephone number noted below.

The Director is hereby authorized to charge any fees, or credit any overpayment, associated with this communication, including any extension fees, to Deposit Account No. 22-0185.

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Respectfully submitted,

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